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Customer Number

PATENT
Docket No.: 58232US004

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

KEITH B. GORDEN, XIAOHONG QUI
and JOHN P. VASILAKOS

Serial No.: 10/777,310
Filed: February 12, 2004

For: METHODS AND
COMPOSITIONS RELATED TO
IRM COMPOUNDS AND TOLL-
LIKE RECEPTOR 8

Group Art Unit: 1615

Examiner:

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

Pursuant to 37 CFR §§ 1.56, 1.97, and 1.98, enclosed is a completed Form PTO-1449, citing references submitted for consideration by the Examiner. Copies of any cited foreign patents, non-patent literature, and unpublished US application documents are enclosed. Pursuant to the waiver in the Pre-OG Notice, dated July 25, 2003, copies of US patents and published US patent applications are no longer required and are not enclosed. It is respectfully requested that the Examiner initial and return the enclosed Form PTO-1449 to indicate that each reference has been considered.

Should a First Office Action on the merits be mailed prior to the filing of this Disclosure Statement, please charge the requisite \$180.00 fee (pursuant to 37 C.F.R. §§ 1.97(c) and 1.17(p)) to Deposit Account No. 13-3723.

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I HEREBY CERTIFY THAT THIS CORRESPONDENCE IS BEING DEPOSITED
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P.O. BOX 1450
ALEXANDRIA, VA 22313-1450 ON
August 12, 2004
SIGNED *Garry L. Hansen*

Applicants submit that the above references, whether taken alone or in combination with each other neither anticipate nor render obvious the present invention. Consideration of the foregoing in relation to the captioned application is respectfully requested.

Respectfully submitted,



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Attorney for Applicants

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Dated: *August 12, 2004*

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U.S. Patent Documents

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		Doc. Number (Kind Code if Known)			
	A1	US- 4,689,338	08-25-1987	Gerster	
	A2	US- 4,698,348	10-06-1987	Gerster	
	A3	US- 4,929,624	05-29-1990	Gerster et al.	
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	A16	US- 5,446,153	08-29-1995	Lindstrom et al.	
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Date Considered:

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

Information Disclosure Statement — PTO-1449 (Modified)

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	A58	US- 6,558,951 B1	05-06-2003	Tomai et al.	

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	B1	EP	0 394 026	10-24-1990			X
	B2	EP	1 104 764 A1	06-06-2001			X

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	B22	WO	02/102377 A1	12-27-2002			X
	B23	WO	03/020889 A2	03-13-2003			X
	B24	WO	03/043572 A2	05-30-2003			X
	B25	WO	03/045391 A1	06-05-2003			X
	B26	WO	03/103584 A2	12-18-2003			X

OTHER DOCUMENTS (Including Authors, Title, Date, Pertinent Papers, etc.)

Exam. Init.*	Cite No.	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published
	C1	Testerman, et al., "Cytokine Induction by the Immunomodulators Imiquimod and S-27609", <u>Journal of Leukocyte Biology</u> , Volume 58, pp. 365-372, September 1995.

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	C2	Chollet, et al, "Development of a Topically Active Imiquimod Formulation", <u>Pharmaceutical Development and Technology</u> , 4(1), pp 35-43 (1999)
	C3	Brassard et al.; "Interferon- α as an immunotherapeutic protein"; <u>Journal of Leukocyte Biology</u> ; Vol. 71; April 2002; pgs. 565-581
	C4	Izumi et al.; "1H-imidazo[4,5-c]quinoline Derivatives as Novel Potent TNF- α Suppressors: Synthesis and Structure-Activity Relationship of 1-, 2- and 4-Substituted 1H-imidazo[4,5-c]quinolines or 1H-imidazo[4,5-c]pyridines"; <u>Bioorganic and Medicinal Chemistry</u> , Vol. 11, pp. 2541-2550 (2003).
	C5	Homung et al., "Quantitative Expression of Toll-Like Receptor 1-10 mRNA in Cellular Subsets of Human Peripheral Blood Mononuclear Cells and Sensitivity to CpG Oligodeoxynucleotides", <u>The Journal of Immunology</u> , 2002, 168; pgs. 4531-4537.
	C6	Hemmi et al., "Small anti-viral compounds activate immune cells via the TLR7 MyD88-dependent Signaling pathway", <u>Nature Immunology</u> , vol. 3, no. 2; February 2002; pgs. 196-200.
	C7	Medzhitov, "Toll-Like Receptors and Innate Immunity", <u>Nature Reviews Immunology</u> , Vol. 1; November 2001, pgs. 135-145.
	C8	Jurk et al. "Human TLR7 and TLR8 independently confer responsiveness to the antiviral compound R-848", <u>Nature Immunology</u> , June 2002, vol. 3, no. 6; pg. 1.
	C9	Akira et al., "Toll-like receptors: critical proteins linking innate and acquired immunity", <u>Nature Immunology</u> , August 2001, vol. 2, no. 8; pgs. 675-680
	C10	Heil et al.; "Synthetic immunostimulatory compounds activate immune cells via TLR7 and TLR8"; 33th Annual Meeting of the Deutsche Gesellschaft für Immunologie, Marburg 2002 - Abstract C.6

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